IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF	)	
	)	ART UNIT: 1644
Arnold I. Levinson *et al.*	)	
	)	Michael Edward Szperka
APPLICATION NUMBER: 10/518,701	)	
	)	
FILED: September 1, 2005	)	
	)	

TITLE: VACCINES FOR SUPPRESSING IGE-MEDIATED ALLERGIC DISEASE AND METHODS FOR USING THE SAME

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply Brief is being filed in response to the Examiner's Answer mailed May 24, 2010 for the above-identified patent application.

STATUS OF CLAIMS

The present application was filed with Claims 1-31.

Claims 32-73 have been added during prosecution

Claims 4, 9-21, 25, 30, 31, and 38-49 have been canceled.

Claims 1-3, 5-8, 22-24, 26-29 and 32-37, and 50-73 remain pending in the present application and are currently rejected.

The claims on Appeal are pending claims 1-3, 5-8, 22-24, 26-29 and 32-37, and 50-73.

Particularly, Claims 1-3, 5-7, 22-24, stand 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (WO 98/53843) in view of Wang et al. (WO 99/67293) in view of Hollis et al. (US 5,629,415) and in view of Rutter (US Patent 4,769,326).

Claims 1-3, 5-7, 22-24, and 26-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/20038 in view of Wang et al. (WO 99/67293) and in view of Rutter (US Patent 4,769,326).

Claims 1-3, 5-7, 22-24, and 26-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Klysner et al. (US2002/0172673) in view of Wang et al. (WO 99/67293) and in view of Rutter (US Patent 4,769,326).

Claims 8, 32-37, 50, and 58-73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (WO 98/53843) in view of Wang et al. (WO 99/67293) in view of Hollis et al. (US 5,629,415) and in view of. Rutter (US Patent 4,769,326) and further in view of Walls et al. (Nucleic Acids Research, 1993, 21 :2921-2929) as evidenced by Janeway et al. (Immunobiolgy, 3rd edition, Garland Publications, 1997, pages 3:26-3:31).

Claims 8, 32-37, 50, and 58-73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Klysner et al. WO 02/20038 in view of Wang et al. (WO 99/67293) and in view of Rutter (US Patent 4,769,326), and further in view of Walls et al. (Nucleic Acids Research, 1993, 21 :2921-2929) as evidenced by Janeway et al. (Immunobiolgy, 3rd edition, Garland Publications, 1997, pages 3:26-3:31).

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GROUND OF REJECTIONS TO BE REVIEWED ON APPEAL

Whether claims 1-3, 5-7, 22-24, and 26-29 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (WO 98/53843) in view of Wang et al. (WO 99/67293) in view of Hollis et al. (US 5,629,415) and in view of Rutter (US Patent 4,769,326).

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Whether claims 8, 32-37, 50, and 58-73 should be rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/20038 in view of Wang et al. (WO 9/67293) and in view of Rutter (US Patent 4,769,326), and further in view of Walls et al. (Nucleic Acids Research, 1993, 21 :2921-2929) as evidenced by Janeway et al. (Immunobiolgy, 3rd edition, Garland Publications, 1997, pages 3:26-3:31).

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ARGUMENTS

Each of the rejections of the claims relies upon one of Chen et al (WO 98/53843), Klysner (WO 02/20038) and Klysner (US2002/0172673). Appellants have noted in each rejection, that each of Chen et al (WO 98/53843), Klysner (WO 02/20038) and Klysner (US2002/0172673) teach away from the claimed invention. Among the differences between the claimed invention and each of Chen et al (WO 98/53843), Klysner (WO 02/20038) and Klysner (US2002/0172673), the claimed invention provides coding sequences for a fusion protein having a proteolytic cleavage site between the IgE epitope linked and non-IgE T cell epitope while each of Chen et al (WO 98/53843), Klysner (WO 02/20038) and Klysner (US2002/0172673) teach intact fusion proteins which co-deliver both moieties. The introduction of a proteolytic cleavage site would be contrary to the teachings of Chen et al (WO 98/53843), Klysner (WO 02/20038) and Klysner (US2002/0172673). Accordingly, every rejection is flawed because each requires the use of a reference that teaches away from the claimed invention.

In the Examiner's Answer, the Office dismissed Appellants assertion that the references teach away from the claimed invention and therefore, in every case, no prima facie case for obviousness has been established. The lynchpin of the Office's position is that Appellants construction of the term "proteolytic cleavage site" is too narrow and that the broadest reasonable interpretation includes proteolytic cleavage sites which would not result in the cleavage of the fusion protein under physiological conditions.

Appellants note the recent Federal Circuit's decision in *In re Suitco Surface, Inc.* (Fed. Cir. Case No. 2009-1418), in which the court stressed that the broadest reasonable interpretation must be reasonable. The court, citing *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007), stated the broadest reasonable construction must be consistent with the specification.

In the instant application, the Office's interpretation of "proteolytic cleavage site" is not reasonable in view of the specification. The specification notes in paragraph 0036 of the published application:

> Regardless of the modality, compositions useful in the invention generally comprise a non IgE helper T cell epitope to provide T

> cell to induce an effective immune response, either as part of the target protein and/or as a separate protein. If the non IgE helper T cell epitope is part of a fusion protein that is the target protein, the fusion protein may preferably contain proteolytic cleavage sites between the membrane IgE epitope and the non IgE helper T cell epitope. The non-IgE helper T cell epitope is preferably tetanus toxoid helper T cell epitope. If the vaccine is provided and a nucleic acid molecule, a nucleotide sequence is provided that encodes a non IgE helper T cell epitope, preferably tetanus toxoid helper T cell epitope. Thus, some aspects of the invention comprise nucleic acid molecule that encode the target protein and a non IgE helper T cell epitope. Some aspects of the invention relate to composition comprising two nucleic acid molecules, one that encodes the target protein and one that encodes a non IgE helper T cell epitope. If the vaccine is provided and a protein based vaccine, a protein is provided that comprises a non IgE helper T cell epitope, preferably tetanus toxoid helper T cell epitope. Thus, some aspects of the invention comprise the target proteins that comprise a non IgE helper T cell epitope. Some aspects of the invention relate to composition comprising two protein molecules, the target protein and a non IgE helper T cell epitope.

The specification thereby is indicating that the membrane IgE epitope and the non IgE helper T cell epitope can function as a fusion protein or as separate proteins and that when provided as a fusion protein, it is preferred that a proteolytic cleavage site be provided between the membrane IgE epitope and the non IgE helper T cell epitope.

One skilled in the art would not reasonably conclude that the proteolytic cleavage site provide may be one that may or may not be functional when the invention is practiced. One skilled in the art, reading the specification, would conclude that the inclusion of the proteolytic cleavage site is to effect the separation of the membrane IgE epitope and the non IgE helper T cell epitope. The Office's interpretation is not reasonable. The proteolytic cleavage site is provided in the claimed invention as a functional element intended to allow for the separation of the membrane IgE epitope from the non IgE helper T cell epitope in vivo as an alternative to provided two separate genes or proteins.

The interpretation offered by the Office is not consistent with the specification and is therefore unreasonable. When read in the context of the specification as a whole, the interpretation offered by the Office is unreasonable.

When the claims are properly construed, it is clear that one having ordinary skill in the art would not combine inclusion of a proteolytic cleavage site with the teachings of any of Chen, Klysner or Klysner. Chen, Klysner or Klysner teach intact fusion proteins and it would be contrary to their teachings to insert a proteolytic cleavage site as discussed in the specification.

In light of the arguments and points discussed in the Appeal Brief filed March 1, 2010 and above, each rejection presented in the January 23, 2009 Office Action should be reversed as each rejection is based upon a primary reference that teaches away from the presently claimed invention and therefore would not be combined with the other cited references to render the invention obvious. The pending claims are allowable, and Appellant respectfully requests that the Board so rule.

Appellant has filed herewith the appropriate payment of fees as required. The Commissioner for Patents is hereby authorized to charge any additional fees, or any difference in fees, which may be required to Deposit Account No. 50-0436. Please refund any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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